

REMARKS

Claims 1-5, 8, 17, 47-51, 57, 58, 63, 64, and 69-77 are pending in the application and have been examined. Claims 1-5, 8, 17, 47-51, 57, 58, 63, 64, and 69-77 stand rejected. Claims 57 and 64 have been canceled. Reconsideration and allowance of Claims 1-5, 8, 17, 47-51, 58, 63, and 69-77 are respectfully requested.

1. The Rejection Under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 1-3, 8, 17, 47-51, 57, 63, 64, and 69-71 under 35 U.S.C. § 102(b) as being anticipated by Koegler et al. (1996) *Biotechnol. Prog.* 12(6):822-36. According to the Examiner, Koegler et al. discloses all the limitations of the claimed devices and methods, including "means for dynamically controlling the voltage applied to the electrode array." Applicants respectfully disagree.

In order for a reference to anticipate a claimed invention, it must provide an enabling disclosure. M.P.E.P. § 2121.01 (8th ed. Aug. 2001, rev. May 2004). As recently articulated by the Federal Circuit, "[t]he disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation." *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 68 U.S.P.Q.2d 1373, 1376 (Fed. Cir. 2003). See also M.P.E.P. § 2121.01. Applicants respectfully submit that Koegler et al. does not provide an enabling disclosure of means for dynamically controlling an electric field gradient.

As noted in the specification, dynamically controlling an electric field gradient refers to maintaining and adjusting the electric field gradient during the course of solute focusing and/or separation (Specification, page 8, lines 14-16). Koegler et al. disclose a method and apparatus for field gradient focusing, in which "the field gradient is created by varying the area through

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which the electric current flows" (Koegler et al., page 824, Col. 1, second paragraph). This represents a fixed field gradient design (see Specification, page 21, lines 16-17). Although, as noted by the Examiner, the "Future Directions" section of Koegler et al. states that "it is possible to manipulate the electric field gradient from outside the column by using a plurality of independent electrodes instead of the shaped chamber described in this paper," and that "this allows the possibility that the field could be dynamically 'shaped' during a run to improve performance," this in no way provides an enabling disclosure of maintaining and adjusting the electric field gradient during the course of solute focusing and/or separation. In fact, the speculative nature of this section of Koegler et al. is confirmed by the next sentence, which states that "one can *imagine* a scenario where the field gradient is steep during the sampling period of a run to speed loading . . ." (Koegler et al., page 835, Col. 2., second paragraph, emphasis added). As noted above, to provide an enabling disclosure "mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation." Koegler et al. does not disclose or suggest any means for dynamically controlling an electric field gradient, but merely "imagines" that it may be accomplished sometime in the future. Undue experimentation would be required to produce a dynamically "shaped" field for separating or focusing charged solutes based on the disclosure of Koegler et al. For example, Koegler et al. does not disclose or suggest the correct geometry, spacing, and composition of electrodes needed to achieve separation and focusing of solutes in an electric field gradient. In contrast, the present invention addresses these issues and provides means for creating dynamic electric field gradients by manipulating the field strength between each pair of adjacent electrodes (Specification, page 21, lines 15-22; page 24, line 13, to page 26, line 19). With respect to Claims 70 and 71, which recite that the electrode array is two-dimensional, applicants respectfully point out that Koegler et al. neither discloses nor suggest a two-dimensional array of electrodes.

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For the reasons described above, Koegler et al. does not anticipate the claimed invention. Applicants respectfully request withdrawal of this ground of rejection.

2. The Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 4, 5, 58, 72, 74, and 76 under 35 U.S.C. § 103(a) as being obvious over Koegler et al. (1996) *Biotechnol. Prog.* 12(6):822-36 in view of U.S. Patent No. 5,298,143 (Ivory et al.). In addition, the Examiner has rejected Claims 73, 75, and 77 under 35 U.S.C. § 103(a) as being obvious over Koegler et al. in view of Ivory et al. as applied to Claim 72, and in further view of U.S. Patent No. 4,670,119 (Hurd), U.S. Patent No. 6,013,168 (Arai), or U.S. Patent No. 5,582,701 (Cabilly et al.), respectively. Applicants respectfully disagree.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness. There are three requirements for establishing a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Third, the prior art reference must teach or suggest all the claim limitations.

According to the Examiner, it would have been obvious to modify the device and method of Koegler et al. by using the linear array of electrodes and the controller comprising a plurality of controller units in communication with the electrode array disclosed in Ivory et al. Applicants respectfully disagree.

Applicants submit that there is no suggestion or motivation in Koegler et al. or Ivory et al., or in the knowledge available to one of skill in the art, to modify the devices and methods of Koegler et al. by using the linear array of electrodes and the controller comprising a plurality of controller units in communication with the electrode array disclosed in Ivory et al. Importantly,

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the separation chamber used in Koegler et al. is very large (a dialysis tube 6 mm in diameter). Smaller tube dialysis membranes were not available at that time. One skilled in the art would have realized that the use of the linear array of electrodes disclosed in Ivory et al. in the device of Koegler et al. would have resulted in severe peak smearing. In fact, a ring of symmetric circular electrodes would be required in the device of Koegler et al. in order to avoid such smearing. In addition, one skilled in the art would have been aware that there might be nonlinear instability in the controller when the electrodes were activated in the separation system buffer. For the same reasons, there would have been no reasonable expectation of success in combining the device and method of Koegler et al. with the electrodes and controller disclosed in Ivory et al.

Therefore, the cited references, either alone or in combination, fail to teach, suggest, provide any motivation to make, or otherwise render obvious the claimed invention. Withdrawal of this ground of rejection is respectfully requested.

### 3. The Rejection Under 35 U.S.C. § 101

The Examiner has rejected Claims 57 and 64 under 35 U.S.C. § 101 as claiming the same invention as recited in Claims 38 and 42 of prior U.S. Patent No. 6,277,258. Claims 57 and 64 have been canceled. Accordingly, this ground of rejection is now moot.

### 4. The Obviousness-Type Double Patenting Rejection

The Examiner has rejected Claims 1-5, 8, 17, and 70 under the doctrine of obviousness-type double patenting as being unpatentable over Claims 7-12 and 21 of U.S. Patent No. 6,277,258 in view of Ivory et al. or Koegler et al. In addition, the Examiner has rejected Claims 47-51, and Claim 58, under the doctrine of obviousness-type double patenting as being unpatentable over Claims 32-36 and Claim 37, respectively, of U.S. Patent No. 6,277,258 in view of Ivory et al. or Koegler et al. The Examiner has also rejected Claims 72, 74, and 76 under the doctrine of obviousness-type double patenting as being unpatentable over Claim 7 of U.S.

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Patent No. 6,277,258 in view of Ivory et al. or Koegler et al. Furthermore, the Examiner has rejected Claims 63 and 69 under the doctrine of obviousness-type double patenting as being unpatentable over Claims 38 and 42 in view of Claim 25 of U.S. Patent No. 6,277,258. Moreover, the Examiner has rejected Claim 71 under the doctrine of obviousness-type double patenting as being unpatentable over Claim 32 of U.S. Patent No. 6,277,258. Also, the Examiner has rejected Claims 72, 74, and 76 under the doctrine of obviousness-type double patenting as being unpatentable over Claim 7 of U.S. Patent No. 6,277,258 in view of Ivory et al. or Koegler et al. Finally, the Examiner has rejected Claims 73, 75, and 77 under the doctrine of obviousness-type double patenting as being unpatentable over Claim 7 of U.S. Patent No. 6,277,258 in view of Ivory et al. or Koegler et al. and in further view of Hurd, Arai, and Cabilly et al., respectively.

Without acquiescing in the Examiner's position, a terminal disclaimer will be filed upon notification of allowable subject matter. Applicants respectfully request these grounds of rejection be held in abeyance pending resolution of the remaining issues.

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Conclusion

In view of the above amendments and foregoing remarks, applicants believe that Claims 1-5, 8, 17, 47-51, 58, 63, and 69-77 are in condition for allowance. If any issues remain that may be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicants' attorney at 206.695.1783.

Respectfully submitted,

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